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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,858	03/14/2002	Bonnie M. Davis	U 013913-4	4479

140 7590 05/27/2004

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,858	DAVIS, BONNIE M.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *5-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/28/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of claims directed to the use of the compound Galanthamine is acknowledged. Claims 1-4, 37-39 are directed to this species. Claims 5-36 are withdrawn from further consideration as being drawn to a nonelected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al US Patent 4,663,318.

Davis teaches the use of Galanthamine for treating Alzheimer disease at the doses of about 5-25 mg a day. (see col 2, lines 45-65; cols 3-4). Galanthamine is a cholinesterase inhibitor; thus, it modulates the activity of nicotinic receptors. Davis treats individuals in need of Galanthamine therapy in effective doses; thus, he inherently disclose methods of treating the effects of low LDL-cholesterol values in the brain on cognitive performance or CNS function by modulating nicotinic receptors for at least claims 1, 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis, Kvipelto et al, (BMJ, Vol 322, 16 June 2001) and Simons et al, (Neurology 2001;57:1089-1093).

The scope of the instant claims encompasses such elderly population that may suffer from both conditions hyperlipidemia and Alzheimer disease. Thus, any patient within such population that receives HMG-CoA treatment for hyperlipidemia and Galanthamine for their Alzheimer would meet the process steps of the instant claims.

The teachings of Davis are described above. Davis teaches the use of Galanthamine for treating Alzheimer which is a disease associated with advance of age and increase level of cholesterol.

To establish that there is at least a sub-population within the geriatric population suffers from both hyperlipidemia and Alzheimer, Examiner draws applications attention to the articles by Kivipelto and Simons.[1]

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[1] See Kvipelto et al, BMJ, Vol 322, 16 June 2001, at pages 1447, 1449-1450. Aso see Simons et al, Neurology 2001;57:1089-1093 at for example page 1091, 2nd-4th para.

Kivipelto shows that advancing age leads to increase cholesterol concentrations, which eventually leads to higher risk of Alzheimer disease. Kivipelto in table 2, and para 1 and 2 of page 1449 describes that high cholesterol concentrations are significant risk factors for Alzheimer's disease.

Simons show that at least in risk of developing Alzheimer is lower in patients that receive Statins for treating hyperlipidemia. (see Simon at pages 1091-1092). The use of Statins at clinically significant levels of cholesterol values is well within the level of ordinary skill in the art. Simon already attests that there are studies wherein patients with AD are also receiving statins. Accordingly, Statins are not only useful for treating high cholesterol but also for lowering the risk of patients at risk to develop Alzheimer.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add to the drug regimen of elderly patients who suffer from Alzheimer and are already receiving statins for their hyperlipidemia, as described by Simon and suggested by Kivipelto, sufficient doses of galanthamine, because as described by Davis, the ordinary skill in the art would have had a reasonable expectation of success in observing improvement of their Alzheimer.

Conclusion

No claims are allowed at this time.

Examiner notes that adding such limitations to the instant claims directing the instant methods to positive recited method steps of determining the LDL- values in the brain, and administering Galanthamine to patients having a value of less than 109 mg/dl LDL-cholesterol could advance the prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RUSSELL TRAVERS
PRIMARY EXAMINER